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Re-evaluation Note REV2013-10

Re-evaluation Project Plan for Pyridaben

(publié aussi en français)

19 November 2013

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

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Canada

ISSN: 1925-0630 (print)
1925-0649 (online)

Catalogue number: H113-5/2013-10E (print version)
H113-5/2013-10E-PDF (PDF version)

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In Canada, pyridaben is under re-evaluation by Health Canada's Pest Management Regulatory Agency (PMRA). The PMRA's pesticide re-evaluation program considers potential risks as well as the value of pesticide products to ensure they continue to meet standards of modern science and current policy established to protect human health and the environment. Under the authority of Section 16 of the *Pest Control Products Act*, the registrant of pyridaben was notified of the initiation of the re-evaluation of pyridaben. Following this, the registrant of the pyridaben technical grade active ingredient in Canada indicated their intention to support all uses included on the labels of commercial products in Canada. This Re-evaluation Note outlines a project plan and timeline for review, as well as summarizes the anticipated areas of focus related to the re-evaluation of pyridaben.

Pyridaben is an insecticide and acaricide that has been registered in Canada since 1997. Pyridaben is currently registered for greenhouse food and non-food crops, terrestrial food/feed crops and ornamentals (Use-Site Categories 5, 6, 13, 14 and 27). Registered pyridaben end-use products are formulated as wettable powder, to be applied using field sprayers or hand-held spray equipment.

The project plan discussed below outlines the anticipated areas of focus and risk assessments required to complete the re-evaluation of pyridaben, as well as additional data required. Should additional information that affects the regulatory status of pyridaben become available during the re-evaluation period, the Agency will reconsider the areas of focus and risk assessments required. Currently, a proposed re-evaluation decision for pyridaben is anticipated to be published in 2014.

Re-evaluation Project Plan

Human Health Risk Assessment

The toxicology database for pyridaben was considered complete at the time of initial registration. Data generated since the time of the original submission (for example, a developmental neurotoxicity study) and data previously unavailable, but that may impact the hazard assessment, will be evaluated. Verification of the points of departure in the toxicology studies as well as those used for risk assessment will be undertaken. Areas not addressed in the original evaluation (for example, establishment of an acute reference dose, application of the *Pest Control Products Act* factor) will be reviewed. Recent scientific literature suggesting a link between pyridaben and Parkinson's Disease will be evaluated.

The dietary exposure and risk assessment previously conducted to support the registered uses will be verified to ensure they continue to meet current science standards and approaches. In particular, the dietary exposure assessment will be updated to reflect current data including new food consumption data and residue data from surveillance programs conducted by the Canadian Food Inspection Agency and the United States Department of Agriculture. The risk assessment will be updated to reflect any revised reference doses (acute reference dose and acceptable daily intake), if applicable.

The occupational exposure and risk assessments will be revised to reflect the currently available scientific data and approaches. Available dislodgeable foliar residue data are being requested to conduct refined post-application worker assessments, which are required for this active.

A residential assessment from commercial application in residential areas will be conducted, including an aggregate assessment of exposures from the diet (food and drinking water) and residential exposures.

Environmental Risk Assessment

Environmental risk assessments will be updated, where appropriate, using current methodologies, available scientific data and relevant scientific literature.

Environmental risk mitigation measures will be reviewed to ensure consistency with current label requirements.

Buffer zones for the protection of sensitive terrestrial and aquatic habitats will be calculated based on current practices and taking into consideration currently registered uses.

The Toxic Substances Management Policy will be taken into consideration.

Environmental fate will be reviewed to determine drinking water and expected environmental concentrations for risk assessment purposes.

Value

The value of pyridaben will be considered. The viability of alternatives will be examined if risks of concern are identified.

Data Requirements

Additional data requirements related to toxicology, occupational exposure and environment assessments have been identified for pyridaben and were requested from the technical registrant (Appendix I).

Anticipated Timeline for Re-evaluation

A proposed re-evaluation decision for pyridaben is anticipated to be published for consultation in 2014.

Additional Information

PMRA documents can be found in the Pesticides and Pest Management portion of the Health Canada website at healthcanada.gc.ca/pmra. PMRA documents are also available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); fax: 613-736-3798; e-mail: pmra.infoserv@hc-sc.gc.ca.

Appendix I Data Requirements for the Re-evaluation of Pyridaben

Toxicology

DACO 4.2.1 Acute Oral
DACO 4.2.2 Acute Dermal
DACO 4.5.4 Genotoxicity: Bacterial Reverse Mutation Assay
DACO 4.5.8 Other Genotoxicity Studies
DACO 4.5.9 Metabolism/Toxicokinetics in Mammals (laboratory animals)
DACO 4.5.14 Developmental Neurotoxicity
DACO 4.8 Other Studies/Data/Reports

Occupational, residential and bystander exposure

DACO 5.9 Dislogeable Residues (Foliar, Soil and Surface)

Environment

DACO 8.2.3.4 Biotransformation in Soil
DACO 8.2.3.5 Biotransformation in Aquatic Systems